UPDATE

FDA Issues Public Health Warning on Phenylpropanolamine

The Food and Drug Administration (FDA), is taking steps to remove phenylpropanolamine (PPA) from all drug products and has requested that all drug companies discontinue marketing products containing PPA. The FDA issued a public health advisory concerning the risk of hemorrhagic stroke or bleeding into the brain, associated with phenylpropanolamine hydrochloride.

PPA is an ingredient used in many over-the-counter (OTC) and prescription cough and cold medicines as a decongestant and in OTC weight loss products.

Adverse events reported with these products led to concerns that this ingredient might increase the risk of hemorrhagic strokes. Manufacturers of products containing PPA worked with the FDA to plan a research program to clarify whether any increase in risk exists.

Scientists at the Yale University School of Medicine conducted the study in which the researchers found an association between PPA use and stroke in women. The increased risk of hemorrhagic stroke was detected among women using the drug for weight control and for nasal decongestion, in the 3 days after starting use of the medication. Men may also be at risk.

The Nonprescription Drugs Advisory Committee met to discuss safety issues related to phenylpropanolamine use and concluded that PPA cannot be considered to be safe for continued use.

The FDA believes that although the risk of hemorrhagic stroke is very low, even with PPA use, the conditions for which these products are used do not appear to warrant an increased risk of this serious event from using this drug. We advise consumers to discuss alternative OTC and prescription products with their health care providers or pharmacists.

Information concerning the history of PPA and the stroke study results can be found on the FDA website at: www.fda.gov/cder/drug/infopage/ppa/default.htm.

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